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Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fishers Lane, Room 11-44 Rockville, MD 20857

RE: Monopril FDA Docket No. 91E-0225

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Term Extension of U.S. Patent No. 4,337,201 issued June 29, 1982. The application was filed on June 3, 1991, under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156(d)(2)(A).

C. E. Van Hom

Charles E. Van Horn

Patent Policy and Programs Administrator Office of the Assistant Commissioner for Patents

cc: Donald J. Barrack
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